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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/083,793	05/22/1998	BRIAN R. MURPHY	17634-000320	4558

7590 11/17/2003

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EXAMINER

CHEN, STACY BROWN

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/17/2003

38

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/083,793

Applicant(s)

MURPHY ET AL.

Examiner

Stacy B Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-94 and 96-143 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-94 and 96-143 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 1998 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed July 21, 2003 is acknowledged and entered. Claims 1-94 and 96-143 are pending and examined. In the Office Action mailed February 21, 2003, it was requested that a copy of the originally filed claims be provided by Applicant. Applicant acknowledged this request in the response filed July 21, 2003, however, it appears that a copy of the Murphy Declaration (CFR 1.132) was sent instead. The Office requests that a copy of the originally filed claims be provided.
2. The objection to claims 90 and 142 is withdrawn in view of Applicant's amendment. The rejection of claims 10-47, 90, 115, 118-128, 133-134 and 142-143 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendments. The provisional rejections of claims 1-94 and 96-143 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over U.S. serial numbers 09/458,813, 09/459,062 and 09/424,628, are withdrawn in view of the terminal disclaimer filed July 21, 2003.
3. The terminal disclaimer filed on July 21, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on U.S. serial numbers 09/458,813, 09/459,062 and 09/424,628, has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections Reinstated - 35 USC § 102 and 35 USC § 103

4. Upon further consideration and review of the Murphy Declaration filed under 37 CFR 1.132, submitted August 26, 2002, the following rejections are reinstated. The Office regrets any

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inconvenience to Applicant, however upon review of the claims and the Murphy Declaration, the art rejections of record are reinstated.:

- The rejection of claims 1-4, 6, 7, 10-17, 20, 21, 26, 27, 30, 33-40, 43, 44, 47-49, 52, 54, 56, 57, 59, 61-85, 88-91, 93, 94, 96-116, 118 and 120-143 under 35 U.S.C. 102(e) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Belshe *et al* (5,869,036) is reinstated, for reasons of record.
- The rejection of claims 51 and 53 under 35 U.S.C. 103(a) as obvious over Belshe *et al* is reinstated, for reasons of record.
- The rejection of claims 18, 19, 28 and 29 under 35 U.S.C. 102(e) as anticipated by Belshe *et al*, or in the alternative, under 35 U.S.C. 103(a) as obvious over Belshe *et al* in view of Stokes *et al* (*Virus Research*, 1993) is reinstated, for reasons of record.
- The rejection of claims 22-25, 31, 32, 42, 60, 117 and 119 under 35 U.S.C. 103(a) as obvious over Belshe *et al* in view of Conzelmann (*J. Gen. Vir.*, 1996) is reinstated, for reasons of record.

Murphy Declaration filed under 37 CFR 1.132

5. The Murphy Declaration, submitted August 26, 2002, and Applicant's arguments have been carefully considered. The rejections hinging on the enablement/non-enablement of Belshe (5,869,036) are addressed in the Declaration.

Paragraphs 1-9 of the Declaration discuss the author of the Declaration and the enablement and art rejections of record at the time the Declaration was submitted. The author,

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Dr. Brian R. Murphy, M.D. is an interested party in the present patent application whose opinion therefore has lower probative value. The inventor discusses the non-enablement of the Belshe patent claims. (The Belshe patent claims are drawn to a hybrid virus comprising an enveloped, negative-sense, single-stranded RNA virus having a genome including a nucleic acid sequence that encodes surface antigens of an RNA target virus (HPIV-1, HPIV-2 and RSV), and a nucleic acid sequence which encodes a variant HPIV-3 L protein conferring attenuation. The L protein has polymerase activity and two substitutions in the amino acid sequence relative to the L protein of the wildtype HPIV-3JS, at residues 942 and 992.)

35 U.S.C. 282 and the MPEP 1701 state that “[a] patent shall be presumed valid”. The Office is barred from questioning the validity of a patent claim, and therefore the enablement of a patent claim. The Murphy declaration would have the Office question the validity of the Belshe patent, which the Office is barred from considering. Notwithstanding the previous points, the declaration further fails to persuade because the standard for enablement for a reference is that the reference teach how to make the invention, not use the invention. The standard for the enablement of a reference is lower than an application’s claim. (See *In re Schoenwald*, 964 F.2d 1122, 22 U.S.P.Q. 2d 1671 (Fed. Cir. 1992).

In paragraph 7, Declarant states that Belshe did not recover “an actual recombinant PIV”. However, Belshe did recover a recombinant PIV by another method other than via cDNA, as accomplished by Applicant. Example 6 (column 17) of Belshe discloses that cp45 virus replicated in L-gene-transfected CV-1 cells was produced, recovered, examined and found to maintain the temperature sensitive property of the cp45 virus. Applicant’s claims are directed to a product, a species of which has been made by other means than cDNA. The process by which

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the product is made does not render the product novel and unobviousness. Paragraph 10 of the Declaration correctly states that "the Belshe et al. specification fails to provide a single example of a recombinant PIV recovered from a cDNA". The Office agrees that Belshe did not teach the recovery of PIV from cDNA, however, a product is a product, regardless of the means by which it was made. Paragraph 10 begins a discussion of the technical support for Declarant's conclusion that the Belshe patent claims are non-enabled. The value of a technical opinion is limited to the assessment of facts leading to the obviousness conclusion, but the obviousness conclusion is a legal matter decided by the Office. The specification claims unexpected results – the recovery of recombinant PIV from cDNA. The instant claims are not commensurate in scope with the recovery of recombinant PIV from cDNA. That which the prior art discloses cannot be considered unexpected. A recovered, recombinant PIV is within the scope of the instant claims. Belshe's hybrid cp45 attenuated virus falls within the scope of Applicant's claims.

Paragraphs 12-15 discuss the scientific deficiencies of Belshe's work, such as lack of controls, lack of verification and validation, low virus production, *in vitro* versus *in vivo* differences in attenuation, and other technical features related to recovery of PIV. Declarant points out the possible complications with Belshe's method of recovery. The Office does not require absolute scientific assurance with regard to a reference which discloses successful production of a compound. Quite the contrary, substantive evidence is required to establish that such a disclosure is in fact not correct. Establishing that Belshe's assays were not scientifically reliable fails to meet the burden of substantive evidence of the negative. In other words, Belshe is taken to mean what Belshe discloses. In paragraph 13, Declarant further states that "even if the complementation is accepted as authentic, it is of such a low efficiency that its significance is

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highly doubtful". Applicant should note that such an argument is not commensurate in scope with the product claims. Also, enablement of a reference is based on success, not the degree of success.

Paragraphs 16-26 detail the difficulties and complexities of recovering recombinant, infectious, PIV from cDNA. Notably, the arguments are focused on the recovery of PIV from cDNA. Declarant's arguments regarding attenuating mutations, precise sequences free of errors (viable), the specific length and strict adherence to the rule of six, construction of a cDNA and expression plasmid, replication competence of virus derived from cDNA, are not commensurate in scope with the claims. The claimed viruses are anticipated and obvious over the prior art, regardless of the method by which they are produced. The methods do not recite the element of recovery from cDNA. Regardless of Belshe's deficiencies regarding recovery of PIV from cDNA, Belshe did in fact recover a recombinant PIV by other means.

Paragraph 27 discusses the enablement of the instant claims. As indicated in the previous Office Action, the enablement rejection has been withdrawn.

In view of the above analysis of the Murphy Declaration, the Office has reinstated the prior art rejections. In summary, the claims are drawn to a recombinant PIV and methods of obtaining the PIV. Declarant's arguments are centered on Belshe's inability to recover recombinant PIV from cDNA. The Office recognizes the deficiencies of Belshe with regard to recovery of PIV from cDNA, however, the instant claims as written do not require cDNA recovery. Therefore, the Declaration fails to persuade the withdrawal of art rejections previously of record and reinstated in this Office action.

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Conclusion

6. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 872-9306. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SBC

Stacy B. Chen
November 3, 2003

James C. Housel
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